The National Medicinal Plants Board (NMPB) in collaboration with the Quality Council of India (QCI), has developed a Voluntary Certificate Scheme for Medicinal Plant Produce based on Good Agricultural Practices (GAP) and Good Field Collection Practices (GFCP) to enhance the confidence in the quality of India's medicinal Plant produce and make available good quality raw material to the AYUSH Industry. Indian Society for Certified Organic Products (ISCOP), as a registered society is a legal entity accredited as per VCSMPP standards to offers services in India. ISCOP assess producers, collectors, groups and traders to comply with the GAP and GFCP standard requirements and the amendments made by the accreditation body time to time in the form of notifications, advisories or any other means. Good Agricultural Practices (GAP) and Good Field Collection Practices (GFCP) standards are available free on NMPB's (www.nmpb.nic.in) as well as in ISCOP website for you reference (www.iscop.org).

This document covers the certification process of medicinal plants based on Good Agricultural Practices (GAP) and Good Field Collection Practices (GFCP) in the wild or intermediate entity like a trader.

Scope of Our Certification Services

The following options are available for certification:

Level 1: Compliance to Good Agriculture Practices (GAP) for producers and Good Field Collection Practices (GFCP) for collectors with identification of species by TLC profiling, wherever needed, and testing for contaminants.

Level 2: Compliance to the requirements for Level 1 and requirements for medicinal plants as per API/UPI/HPI etc as applicable

a) **Option 1 -** Individual producer/collector applies for certification and gets certification for his/her produce.

b) **Option 2 -** A producer/collector group applies for group certification and the producer/collector group, as a legal entity, gets certification.

c) **Option 3 -** The individual farmer may opt for lot wise certification model based on GAP where he/she gets certificate of conformity of the lot of produce submitted to approved certification body for inspection.

d) **Option 4** – An intermediate entity like a trader applies for certification of the certified medicinal plant produce for proper storage for supplies in the market or to manufacturer/processor of Ayush Products.

VCSMPP - Certification Process of ISCOP

ISCOP takes the operator through a ladder of evaluation before granting certified status. Certification process of ISCOP follows an engagement approach that considers end point analysis and critical control points as two major aspects to operators' status to every step in the engagement process.

ISCOP considers 'awareness' as a primary step to engage the medicinal plant producer/collector/trader to this engagement process of certification. The applicants will be evaluated for their medicinal plant awareness and their ability to understand and prepare a System Plan.

CERTIFICATION PROCESS 1 – FOR INDIVIDUAL FARMER/COLLECTOR

STEP 1: APPLICATION FOR CERTIFICATION OF INDIVIDUAL PRODUCER/COLLECTOR

1.1 Any producer/collector who is a legal person can apply for certification to ISCOP.
1.2 The application shall be made before sowing of the crops/collection.
1.3 All relevant information concerning producers/collectors applying for certification shall be recorded for the producer/collector to become registered. This information will be used to supply the registered party with a unique client number, which will be used as a unique identifier for all certification activities.
1.4 The information required is consistent with the information of Certification Agreement signed between the producer/collector and ISCOP.
1.5 The prospective applicant shall apply to ISCOP on the Application form prescribed.
1.6 The prospective applicant shall along with the application declare any judicial proceedings relating to their operations / product, any proceedings by any Regulatory body or suspension / cancellation / withdrawal of any certification / approvals under any Regulations or otherwise.
1.7 Certification is granted only against the latest relevant certification criteria. ISCOP shall review all applications for the above and ensure the same.
1.8 All applications for certification shall be reviewed by us for adequacy and deficiencies observed, if any, and be informed to applicant within seven days of receipt of application.
1.9 The applications found to be complete and supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained.
1.10 Antecedents of applications shall be verified. If punished under the law, the application from the same person will not be entertained during the period of punishment and in any case for at least one year from the date of punishment.
1.11 Applications from farmers/collectors who have earlier either misused the Certification/ certification mark, or whose earlier certificate was cancelled because of violation of terms and conditions/misuse of certification mark will not be entertained within one year of cancellation of the certificate by any CB.
1.12 Applications from farmer/collector found to be misusing the Certification/certification Mark while their application is being processed for grant of certificate, will not be processed any further, and rejected after giving a due notice of 15 days. Fresh applications from them shall be treated as per clause 1.11 given above.
1.13 Requests for grant of certificates from ex-applicants shall be processed like a fresh applicant and the entire procedure for grant of certificate be adhered to.
1.14 ISCOP shall reject or close an application under the following conditions;

a. If Initial Evaluation is not carried out within six months of registration of application,
b. if more than 20% of samples drawn fail on testing during the Initial Evaluation
c. If the follow up evaluation carried out after organization has confirmed necessary corrective actions is not satisfactory
d. Lack of competent personnel for production/collection and handling,
e. If farmer/collector shows no progress towards completion of corrective actions within three months of Initial Evaluation and six months of Registration of application,
f. Misuse of Certification/certification mark,
g. Evidence of malpractice and
h. Voluntary withdrawal of application.

1.15 In the event of a closure/rejection of an Application, the application fee submitted with the application may be refunded as decided by ISCOP.

STEP 2: CERTIFICATION PROCESS FOR INDIVIDUAL FARMER/COLLECTOR 2.1 Control Criteria and Compliance Criteria (CCCC)

The Control Criteria and Compliance Criteria (CCCC) checklist based on respective standards will be used for evaluation.

2.2 Pre-assessment

2.2.1 The applicant may seek a pre-assessment, which is not mandatory, during which ISCOP will check the applicant's state of preparedness for the evaluation, and availability of competent personnel and adequate records of producers/collectors on CCCC.

2.2.2 Deficiencies observed with respect to the certification criteria during the pre- assessment will be informed in writing to the applicant.

2.2.3 There will be only one pre-assessment.

2.3 Initial evaluation

2.3.1 A single stage Initial evaluation will be carried out by a competent evaluation team.

2.3.2 Initial Evaluation of the product and the processes at the site of the applicant will be conducted within three months of registration of application and/or satisfactory fulfilment of all application requirements.

2.3.3 ISCOP will communicate the composition of the team and duration of Initial Evaluation to the applicant for verifying any conflict of interest and any objections to the team composition by the applicant should be examined on merit.

2.3.4 Timings and date of Initial Evaluation will be decided in consultation with the applicant ensuring that processes such as harvesting/collection representative of normal operations are open for witnessing during the planned Evaluations:

a) *Inspection timings*

The inspection of a producer/collector takes place after registration with ISCOP depending on the produce to be inspected. The ideal timing for evaluation of all control criteria will be during harvest time when sufficient records/evidence is available, especially to facilitate verification of the control points related to harvest.

Alternative timing options may be followed where evaluation during harvest time is not possible. The first inspection therefore takes place before or after harvest. Justification for alternative timing may be logistics and time constraints of producer/collector and inspector, variation in harvest dates, perennial crop not yet producing mature produce, etc. Practically, inspection of records and visual evidence requires that the evaluation must take place as close to harvest as possible, for the evaluators to verify as many control points as possible.

b) *First Inspection Timing for Multiple produce Certification*

The producer/collector may be seeking certification for more than one produce, and the produce may not all have the same seasonal timing, i.e. harvest of one produce does not necessarily coincide with the harvest of other produce different harvest timings of medicinal plants is given in Annex of GFCP standard.

Where the medicinal plant produce to be included in the certification scope are concurrent, i.e. harvested at the same time, then the first evaluation will be timed so that at

least one crop can be evaluated at harvest, making an assumption that the other crops getting ready for harvest will be compliant to the same degree.

Where the crops to be included in the certification scope are consecutive, i.e. the production of one crop finalises before the production of the next one commences, then in the first year a full evaluation of the first crop must be made during harvesting. Subsequent crops grown in that same first year can be added to the certificate only when compliance has been verified for each crop, either through a site inspection at harvest of each crop or through data collection and discussion with the applicant.

2.4 Evaluation process

2.4.1 ISCOP's team shall witness the processes covering as many CCCC as possible during evaluation of the applicant. Any nonconformity observed during evaluation with respect to the conformance criteria will be informed in writing to the applicant for taking necessary action. The nonconformities will be classified as critical, major or minor depending on their severity as defined in the respective standards.

2.4.2 A representative sample will be drawn for testing in an independent laboratory. Since there would be several types of produce and with varietal differences, efforts would be made to cover most of the produce during a certification cycle. The specified criteria will be clearly mentioned and communicated to the testing laboratory. The samples(s) will be duly coded and as far as possible, the identity of the manufacturer shall be hidden. The sample(s) will be so despatched that they do not get damaged and or contaminated, undergo deterioration, and the product integrity is maintained the testing laboratory shall test contaminants and conduct TLC profiling, if needed. There may be additional tests needed for Level 2 certification.

2.5 Compliance levels for certification

2.5.1 The producer is required to comply with three types of compliance criteria set out in the GAP/GFCP standard besides the plant requirements as set out in API in order to obtain certification. These are Critical, Major and Minor, which must be fulfilled in all respects before certification.

2.5.2 Compliance is indicated with a "Yes" (for compliant), "No" (for not compliant) on the checklist. Evidence/comments will be provided for each control criteria- these will enable the audit trail to be reviewed after the event, and will include details of references taken during the evaluation. It is, however, obligatory to give evidence /comments for all the critical and major compliance criteria inspected in all external evaluation, selfassessments, and internal evaluation.

2.5.3 The level of compliance shall be established based on the following:

a) Critical- 100% compliance of all applicable critical control points
b) Major- 90% compliance of all major control points is compulsory
c) Minor-75% of compliance of all applicable minor control points is compulsory.
d) Compliance to contaminants
e) TLC profiling, if needed.
f) Testing as per API/HPI etc for Level 2 certification as needed

2.5.4 ISCOP will maintain records of all certification activities- application registration, documents provided by applicant, on site evaluation report, test reports of sample(s) sent for independent testing, and evaluation and review of reports for grant of certification.

2.6 Internal self-assessment quality assurance

The individual producer/collector shall carry out an internal self-assessment at least once a year. This self-assessment shall be carried out under the responsibility of the producer/collector.

The self-assessment shall be against the complete checklist (Critical, Major and Minor) of the applicable scope(s). The completed checklist shall be available on site for review by the evaluator during ISCOPs evaluation.

STEP 3: GRANT OF CERTIFICATION

3.1 ISCOP shall grant certification after ensuring:

a) complete compliance to the Certification Criteria (GAP/GFCP) based on evaluation reports (See 2.4 and 2.5),
b) certification scheme requirements,
c) Compliance to limits of contaminants
d) TLC profiling, wherever needed,
e) conformance to product requirements after testing as per API/HPI etc for Level 2 certification as needed and
f) satisfactory resolution of nonconformities raised. There shall be no conditional grant of certification.

3.2 On grant of certification, ISCOP will inform the farmer/collector and issue a Certificate, uniquely identified, to the farmer/collector indicating the names of the produce certified, the certification criteria against which the certification has been awarded.

3.3 No Brand names will be mentioned on the Certificate document or any other document intimating grant of certification.

3.4 The effective date of certification will not be before the date of decision to grant the certification to the farmer/collector.

3.5 The certificate for produce certification will be for a period of 3 years from the date of decision to grant the produce certification.

3.6Scope of certification

3.6.1The product scope is linked to the location where that product is produced. Certificate is issued to the registered producer/collector, on the farms/in wild where the products are produced and for the products declared. The legal entity of the locations certified must be declared by the certificate holder.

3.6.2The entire production/ collection process of the declared and registered produce must comply with requirements. Certified locations cannot be separated into growing areas or handling facilities that are certified and other growing areas or handling facilities of the same product that are excluded from certification.

STEP 4: SURVEILLANCE EVALUATION

4.1Surveillance evaluations of the certified sites will be carried out at least once a year, ensuring that the gap between two surveillance evaluations does not exceed one year. ISCOP may allow a grace period of one month based on valid grounds beyond which delays will lead to suspension of the certificate. The surveillance would be timed around harvest time of some crop under certification.

4.2The full checklist and verification process will be completed by the evaluator annually. There must be at least one produce registered in the field or in the storage evaluated to give us the confidence that any other registered crops not present at that time, are handled in compliance with the standard.

4.3 ISCOP will ensure coverage of all the CCCC checklist as applicable so that basic operations and their controls are witnessed during the surveillance evaluation. Surveillance planning must keep in view the crop maturity timings to coincide visit with harvest time as for as possible.
4.3In case where the farmer/collector is certified to a number of produce of different types under the same certificate, ISCOP shall plan for surveillance evaluation with a view to covering as much of the entire range of medicinal plant produce during the certification period.

4.4During the surveillance evaluation, the evaluators shall as a minimum check and report on the following;

a) Status of compliance to the requirements of the certification criteria,
b) Internal self-assessment reports,
c) Handling and disposal of nonconforming products,
d) Drawing samples for testing in independent laboratory
e) Actions taken on nonconformities observed during the previous evaluation,
f) Redressal of complaints, if any,
g) Information on production of produce and the names of consignees to whom certified produce have been supplied.

4.5If any nonconformity is observed, the same will be categorized as either a Critical, Major or Minor. The nonconformity report will be provided to the client in writing, generally on site, for correction and corrective action. Details of the same will be reported in the Surveillance evaluation report.

4.6 ISCOP may increase the frequency of surveillances with duly recorded justification for reasons like investigation of complaints, any doubts about continuing adherence to standards prescribed etc.

4.7If the surveillance evaluation results in an infructuous visit due to any reason, ISCOP will conduct another surveillance evaluation. Such additional evaluations may be charged to the certified unit as decided by ISCOP.

STEP 5: MARKET SAMPLES

5.1 Samples of certified produce will be purchased from the market or procured from organized consumers and tested in independent laboratories for ascertaining compliance to requirements of the Certification Criteria.

5.2 ISCOP draws a minimum of one sample for each crop certified during the certification cycle from market as well as onsite - 50% samples will be from market. In case market samples are not available, they will be taken from collector/producers end but it will be resorted to in exceptional situations like exports with recorded justification.

5.3 In case where the farmer/collector is certified to a number of produce of different types under the same certificate, ISCOP will attempt to draw the market samples in a manner so that practically the entire range is covered in sampling within a certification cycle.

5.4 Market samples will be drawn in the original packaging, where practicable and produce integrity shall be ensured by ISCOP.

5.5 Failure of sample of certified produce, drawn from the market, to comply with criteria requirements will be communicated to the certified unit for investigation, root cause analysis and proposed corrective actions within 15 days of intimation. ISCOP will respond to the proposed corrective actions within 5 days and the producer should implement the corrective actions within one month from acceptance of the corrective actions by the CB.

5.6 Depending on the nature of the failure reported, ISCOP shall decide on one or any of the following;

a) Draw additional samples of the produce around the same time from the market,
b) Organize for an additional surveillance evaluation immediately,
c) Increase the frequency of surveillance evaluation,
d) Increase the number of market samples.

The producer/collector will be informed of the decision taken.

5.7 When there is repetitive failure of the sample, ISCOP shall suspend the certification, till adequate and effective corrective actions are taken (See Step 6).

STEP 6: SUSPENSION OF CERTIFICATION

6.1 ISCOP will issue due notice of at least one week for suspension of certification to the unit. In case of serious failures, the notice may not be required.

6.2A Suspension is issued when:

a) two consecutive samples fail to conform to the requirements of the criteria,
b) Unsatisfactory performance during two consecutive Surveillance evaluations on account of any of these aspects is observed:
c) A suspension may also be issued to the producer who voluntarily asks for it, for some (partial) or all (complete) of his products.

6.3 After the Suspension is issued, a time period allowed for correction and corrective action will be set by ISCOP not exceeding 6 months. If the suspension is voluntary, the period for corrections and corrective actions is set by the producer/collector himself, which must be agreed upon with ISCOP, but not exceed 6 months.

6.4 During the period of suspension, the producer will be prevented from using the logo/trademark, Licence/certificate or any other type of document that has any relation to certification.

6.5 The producer/collector unit will be advised to undertake a root cause analysis and identify the necessary corrective actions for resolving the same.

6.6 ISCOP will revoke suspension only when corrective actions have been taken and verified.

6.7 Suspension will not exceed a period of six months. If the cause of the Suspension is not resolved within the time period set, the certification will be cancelled.

STEP 7: CANCELLATION OF CERTIFICATION

7.1A Cancellation shall be issued when:

a) A producer cannot show sufficient corrective action after Suspension has been issued and six months have elapsed,
b) A nonconformity in one scope leads to doubt about the integrity of the produce,

c) Major contractual nonconformities are detected.
d) Certified client contravenes the terms and conditions of certification and provisions of certification scheme like suspension of certificate, inadequate corrective actions, lack of compliance to criteria for Certification etc

7.2 A Cancellation of the contract will result in the total prohibition of the use of the logo/trademark, Licence/certificate.

7.3 A producer that has had a Cancellation applied may not re-submit for certification until 12 months after the date of Cancellation.

7.4 The producer must either resolve the nonconformities communicated or appeal to ISCOP in writing against the nonconformities explaining the reasons for the appeal.
7.5 ISCOP shall cancel the certification at the request of the certified client, if the operation(s) in the certified client's premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc, or closure of operations etc.

STEP 8: RECERTIFICATION

8.1The certificate will be revalidated at the end of every year (See 8.5) depending on the performance of operation of certification but recertification will be at the end of 3 years

8.2 ISCOP will send the recertification notice to the certified client at least four months prior to expiry of certificate validity period.

8.3 The certified farmer/collector shall apply for recertification in the prescribed format along with fee, if any prescribed by ISCOP at least 3 months before expiry of the certification.

8.4 ISCOP will review the performance of the certified client who has sought recertification, with respect to compliance to certification criteria during the certification cycle prior to a decision on the recertification.

8.5 The review shall be based on:

a) The surveillance evaluation reports,
b) Handling and disposition of nonconforming products,
c) Any suspension of certificate during the previous validity period,
d) Corrective actions taken,
e) Complaints, if any received, and
f) Adverse information, if any.

8.6 Recertification will be based on the satisfactory performance of the certified client.There will be no conditional recertification.

8.7 When performance of the certified client is not satisfactory, ISCOPwill withhold the recertification clearly stating the reasons and give time for effecting corrective actions. The verification and decision on recertification shall be taken within 3 months of the expiry date.

8.8 The corrective actions will be verified generally on site unless ISCOP can verify the same off site prior to considering for recertification.

8.9 The recertification shall be affected from the date of the expiry of the previous certificate and the intervening period shall be treated as period of suspension and clearly stated on the Certificate. The certified unit shall not claim certification or use the Certification during this period.

8.10 In case the certified unit does not complete satisfactorily actions within three months, the certificate shall stand expired from the date of expiry of previous validity.

STEP 9: CHANGE OF OWNERSHIP/NAME

9.1 In the event of change of ownership, the new owner farmer/collector shall submit proof of change of ownership. He shall also submit acceptance to the agreement for Certification with ISCOP regarding the operation and payment of fees. The same process shall be followed as and when an existing applicant undergoes a change in ownership. Such changes shall not call for a visit to the site.

9.2 In case of change of name, the applicant/certified client shall inform the change in the name to ISCOP supported with documentary evidence, and if satisfied, ISCOP shall endorse the new name in the application/certificate.

STEP 10: EXTENSION OF SCOPE

10.1 Extension of scope of certificate for inclusion of additional produce, varieties of the under the same certificate shall be done after ascertaining that the certified client has requisite resources required for the new produce/variety and technical skills as evaluated at harvest of that particular produce and samples(s) from new varieties to be included are on independent testing found conforming to requirements of the Criteria.

10.2 The extension of scope will be clearly mentioned in the certificate document along with its date of inclusion for avoiding any misrepresentation or misinterpretation. Irrespective of the date of inclusion, the validity of the Certificate will remain unchanged.

STEP 11: CERTIFICATE

11.1 ISCOP will provide a certification document to the certified client that clearly conveys, or permits identification of:

a) the name and geographic location of the client,
b) the dates of granting, extending or renewing certification,
c) the expiry date or recertification due date consistent with the recertification cycle,
d) a unique identification code,
e) the certification criteria, including issue number and/or revision, against which the product(s) are certified,
f) the scope of certification with respect to product(s) as applicable at the identified site,
g) the name, address and certification mark of ISCOP; other marks (e.g. accreditation symbol) may be used provided they are not misleading or ambiguous,
h) any other information required by the certification criteria used for certification,
i) in the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents

11.2 The effective date on a certification document will not be before the date of the certification / recertification decision.

11.3 The formal certification documentation will include the signature of the individual(s) of the certification body assigned such responsibility.

CERTIFICATION PROCESS 2 – FOR GROUP PRODUCER

STEP 1: CONCEPT OF GROUP CERTIFICATION

1.1 The group shall be registered as a legal entity as Producers Association. This legal entity shall have ultimate responsibility over the production, handling and ownership of the products, thus it is responsible for the compliance with the standard. The legal entity shall enter into a contractual relationship and will have Certification Agreement with ISCOP, and becomes the sole holder of the certificate.

1.2 The administrative structure of the producer group shall be documented and clearly identify the relationship between the producers and the legal entity. There shall be written signed contracts between each producer and the producer group.

1.3 The producer group shall maintain a register of all member producers, and of all the applicable sites used for production in accordance with the standard. All these member producers in the producer register must be registered individually enter into contract with the producer group. The register shall at least contain the following information for each producer:

i) Name of producer, ii) Name of contact person, iii) Full address (physical and postal),

iv) Contact data (telephone number and e-mail and/or fax number), v) Other ID (GST, AADHAAR VAT Number, PAN, etc),

vi) Produce registered vii) Growing/Production area and/or quantity for each registered produce

viii) Internal audit date

ix) Since when the producer is associated with the group. x) Any sanction earlier placed and withdrawn

xi) Producer registration with any Govt. Dept.(The State Medicinal Plant Board etc)

STEP 2: QUALITY MANAGEMENT SYSTEM OF GROUP FACILITY

2.1 Management and Organisation

The producer group shall have a management structure and sufficient suitably trained resources to effectively ensure that the registered producers meet the requirements of GAP on their

production locations. The organisational structure of the group shall be documented and shall include:

i) GAP management representative - person responsible for managing the implementation of GAP in the group. ii) Internal inspector(s)–person(s) responsible for the internal inspections of each producer iii) member of the group- complying with the GAP requirements set for an internal group inspector.
iv) Internal auditor(s)- person(s) responsible for the internal audit of the Quality Management System, complying with the GAP requirements set for an internal group auditor
v) Agricultural technical person – person(s) responsible for technical advice to the group.
vi) Quality Systems Management (QMS) persons – person(s) responsible for managing the QMS.

NOTE: A group needs at least one internal auditor, who can cover the functions of internal group inspector and internal auditor (in case only one internal auditor who performs also the inspections, another person, identified in the QMS must approve the producer internal inspections.

2.2 Responsibility and Duties

The duties and responsibilities of all personnel involved with the compliance of GAP requirements shall be documented, and an individual who holds a position of sufficient seniority and resources to serve as the overall responsible person will be nominated for maintenance of the GAP certification.

2.3Competency and Training of Staff

i) The group shall ensure that all personnel with responsibility for compliance with the GAP standard are adequately trained and meet defined competency requirements. They shall possess degree/diploma in agricultural sciences with suitable training.

ii) The competency requirements, training and qualifications for key staff shall be documented and shall meet any defined competency requirements.

iii) Records of qualifications and training shall be maintained for all key staff (managers, auditors, inspectors, etc.) involved in compliance with GAP requirements to demonstrate competence.

iv) The internal auditor(s) and inspector(s) shall undergo training and evaluation, on the job audits/inspections to ensure consistency in their approach and interpretation of the standard.

Systems shall be in place to demonstrate that key staff is informed and aware of development, issues and legislative changes relevant to the compliance to the GAP standard

Reference- ISO 19011-2011 Guideline for auditing management systems

2.4Quality Manual

2.4.1The group shall have a quality manual containing as a minimum the following:

i) Documented operating and quality management systems related to the GAP standard ii) Policies and procedures shall be sufficiently detailed to demonstrate the group's control of the principal requirements of the GAP standard. iii) Relevant procedures and policies available to the producer group registered members and key staff.

iv) Quality Manual shall be reviewed periodically to ensure that it continues to meet the requirements of the GAP standard and those of the producer group.
v) Incorporation of relevant modifications of the GAP standard that come into force within the time period specified.

2.5Document Control

2.5.1Quality Management System (QMS) Documents

All documentation relevant to the operation of the Quality Management System (QMS) for GAP compliance shall be adequately controlled. This documentation shall include:

i) The Quality Manual ii)
GAP operating procedures
iii) Work instructions iv)
Recording forms
v) Relevant documents of external origin.

2.5.2 Quality Management System Document Control Requirements

i) There shall be a written procedure defining the control of documents. ii) All documentation shall be reviewed and approved by authorised personnel before issue and distribution. iii) All controlled documents shall be identified with an issue number, issue date/review date and be appropriately paged.
iv) Any change in these documents shall be reviewed and approved by authorised personnel prior to its distribution.
v) A copy of all relevant documentation shall be available at any place where the QMS is being controlled. vi) There shall be a system in place to ensure that documentation is reviewed and that following the issue of new documents, obsolete documents are effectively rescinded.

2.6 Records

i) The group shall maintain records to demonstrate effective control of the GAP Quality Management System requirements and compliance with the requirements of GAP standard. ii) Records from the QMS related to compliance of GAP requirements shall be kept for a minimum of 3 years. iii) Records shall be genuine, legible, stored and maintained in suitable conditions and shall be accessible for inspection as required. iv) Records that are kept on-line or electronically are valid. If a signature is required, this can be a password or electronic signature that ensures the unique reference and authorization of the person signing. If a written signature of the responsible person is needed then this must be present. The electronic records must be available during ISCOPs inspections. Back-ups must be available at all times.

2.7 Complaint Handling

i) The group shall have a system for effectively managing customer complaints. ii) There shall be a documented procedure that describes how complaints are received, registered, identified, investigated, followed up and reviewed. ii) The procedure shall be available to customers as required.
iv) The procedure shall cover both complaints to the group and against individual producers.

Reference- ISO 10002:2004 Quality Management Systems - Guidelines for complaint handling in an organization

2.8Internal Audits and Inspections

Internal audit systems shall be in place both to assess the adequacy and compliance of the documented QMS and to inspect the producers and farms against the GAP standard.

2.8.1 Quality Management System Audit

Internal auditor(s), complying with the GAP requirements set for an internal group auditor, shall conduct the internal audit of the QMS.

i) The QMS for the GAP scheme shall be audited at least annually.
ii) Internal auditors shall be suitably trained and independent of the area being audited. iii) ISCOP will evaluate the competence of the internal auditor during the external audit iv) Records of the internal audit plan, audit findings and follow up of corrective actions v) resulting from an audit shall be maintained and available.

NOTE: It is permitted for the same person to initially develop the QMS within the group, and then undertake the required annual QMS audit, however the person responsible for the day-today ongoing management of the QMS is not allowed to undertake the required subsequent annual internal QMS audits.

2.8.2 Producer and Production Location Inspections

Internal inspectors, complying with the GAP requirements set for an internal group inspector will be responsible for carrying out the farm inspections:

i) Inspections shall be carried out at each registered producer and production location at least once a year based on the GAP Checklist. All Critical, Major and Minor control points must be inspected in full. ii) There shall be a process for the review of the inspection reports and producer status. iii) New members of the group must always be internally inspected prior to their entering into the GAP registered producers list.
iv) The original inspection reports and notes shall be maintained and available for inspection as required.
v) The inspection report shall contain the following information

a) Identification of registered producer and production location(s)
b) Signature of the registered producer
c) Date of inspection
d) Inspector name
e) Registered products
f) Evaluation result against each GAP control point
g) All Critical and major points in the Checklist must include details of what was verified in the comments section of the checklist, in order to enable the audit trail to be reviewed after the event.
h) Details of any non-compliances identified and time period for corrective action, i) GAP status
j) Harvest windows for the crop inspected
k) Total extent of land at the location
l) List of plant protection chemicals used for the present crop
m) Any sanction earlier imposed on the producer and subsequently withdrawn
n) Produced sold in the 12 months period prior to the date ofinspection

(vi) The internal auditor / audit team will make the decision on whether the producer is compliant with the GAP requirements, based on the inspection reports presented by the internal inspector.

2.8.3 Non-conformities and Corrective Action Systems

i) There shall be a procedure to handle non-compliances and corrective actions which may result from internal or external audits and/or inspections, customer complaints or failures of the QMS. ii) There shall be documented procedures for the identification and evaluation of non- conformities to the QMS by the group or by its members.
iii) Corrective actions following non-compliances shall be evaluated and a timescale defined for action. iv) Responsibility for implementing and resolving corrective actions shall be defined.

2.9 Product Traceability and Segregation

i) Product meeting the requirements of the GAP standard and marketed as such shall be traceable and handled in a manner that prevents mixing with non-GAP approved products. ii) There shall be a documented procedure for the identification of registered produce and to enable traceability of all product, both conforming and non-conforming to the applicable production sites. A mass balance exercise must be carried out to demonstrate compliance within the legal entity. iii) The produce handling site shall operate procedures which enable registered product to be identifiable and traceable from receipt, through handling, storage and dispatch. iv) Effective systems and procedures shall be in place to negate any risk of mis-labelling or mixing of GAP certified and non-GAP certified products.

2.10 Sanctions and Non-Conformances

i) The group shall operate a system of sanctions and non-conformances with their producers. ii) Contracts with individual producers shall define the procedure for sanctions including the levels of Warning, Suspension and Cancellation.
iii) The group shall have mechanisms in place to notify the ISCOP immediately of Suspensions or Cancellations of registered producers.
iv) Records shall be maintained of all sanctions including evidence of subsequent corrective actions and decision-making processes.

2.11 Withdrawal of Certified Product

i) Documented procedures shall be in place to effectively manage the withdrawal of registered product ii) Procedures shall identify the types of event which may result in a withdrawal, persons responsible for taking decisions on the possible withdrawal of product, the mechanism for notifying customers and ISCOP; and methods of reconciling stock. iii) The procedure shall be capable of being operated at any time. iv) The procedure shall be tested in an appropriate manner at least annually to ensure that it is effective and records of the test retained.

5.2.12Subcontractors

i) Procedures shall exist to ensure that any services subcontracted to third parties are carried out in accordance with the requirements of the GAP standard.
ii) Records shall be maintained to demonstrate that the competency of any subcontractor is assessed and meets the requirements of the standard.
iii) Subcontractors shall work in accordance with the group's QMS and relevant procedures and this shall be specified in service level agreements or contracts.

STEP 3: APPLICATION FOR GROUP CERTIFICATION

3.1 A producer group forming a legal entity can apply for certification to ISCOP. A producer group which enables the application of a Quality Management System across the whole group

of the group's registered producer members comply in a uniform manner with the GAP requirements. The producer group registered members must be legally responsible for their respective production locations.

3.2 The producers group applying for certification must be recorded for the producer group to become registered. This information will be used to supply the registered party with a unique client number, which will be used as a unique identifier for all certification activities.

3.3 Producer Registration information
The information required is consistent with the information of Certification Agreement signed between the producer and ISCOP.

For the registration to be accepted, the producer will have signed the Certification Agreement between ISCOP, a Client number, as well as any registration number the CB may assign and agreed to pay the registration fee.

3.4 The following information must accompany the application:

a) Quality Manual and other related documents,
b) the name and address of applicant
c) proof of legal entity
d) location and total number of registered producers,
e) produce being handled at the group facility,
f) relevant certification criteria GAP/GFCP against which certification is sought,
g) Produce handling and storage area,
h) number and competence of manpower, and
i) covered medicinal produces producer wise.

3.5 Provisions given under Individual farmer/collector 1.7-1.16 shall also apply.

STEP 4: CERTIFICATION PROCESS

4.1 Control Criteria and Compliance Criteria (CCCC)

The Control Criteria and Compliance Criteria (CCCC) checklist based on respective standards shall be used both for internal and external evaluation.

4.2 The Quality Management Compliance Criteria (QMS)

The quality management Systems (See Step 2) of the Producer shall be evaluated with the QMS Checklist

Reference- ISO 9001:2015 Quality Management Systems-Requirements

4.3 Pre-assessment

4.3.1 The applicant may seek a pre-assessment, which is not mandatory, during which ISCOP will check the applicant's state of preparedness for the evaluation, documentation and availability of competent personnel and adequate records of member producers.

4.3.2 Deficiencies observed with respect to the certification criteria during the pre- assessment shall be informed in writing to the applicant.

4.4 Evaluation process

4.4.1 Facility evaluation/audit- The evaluation shall be planned when maximum number of crops in their maturity/zone and they are likely to brought to the group facility for pre-processing and storage. The criteria defined under 2.3 and 2.4 shall apply

4.4.2 ISCOP shall review internal evaluation reports. A minimum of one internal evaluation per annum of each registered producer within the producer group must be carried out by qualified internal producer group evaluators within the producer group or subcontracted to an external verification body, different from the certification body responsible for the external certification evaluation of the group. The internal self assessment inspection shall be based on the complete checklist (Critical, Major and Minor) of the applicable scope(s).
4.4.3 External Quality Management System (QMS) Audit by ISCOP - One announced external audit carried out annually by ISCOP of the registered producer group. ISCOP shall audit the QMS of the Producer Group facility

4.4.4 External Producer Inspection by ISCOP - ISCOP shall select producers by taking a random sample that, as a minimum, is the square root of the total number of registered producers within the producer group. For the first inspection, the square root of the producers in a producer group will be inspected in full by ISCOP. If Producer Group X has 25 registered members, ISCOP sets the square root as the sample, 5 producers (√25) will be inspected at this first inspection.

4.5 Grant of certificate

4.5.1 The certificate compliance shall be issued on conformity with the following requirements:

a) Satisfactory operation of Group facility,
b) complete compliance to the Certification Criteria (GAP/GFCP) based on evaluation report of selected producers
c) Compliance to limits of contaminants as specified in Annex D
d) TLC profiling, wherever needed,
e) conformance to product requirements after testing as per API/HPI etc for Level 2 certification as needed and
f) Satisfactory resolution of nonconformities raised.

4.5.2 On grant of certification, ISCOP shall inform the producer group, the applicant and issue a Certificate, uniquely identified, to the group producer indicating the names of the produce certified, the certification criteria against which the certification has been awarded, effective date, validity date, and the name and address of the producer group.

4.5.3 A list of all the producers and sites to which the certificate relates shall be issued in an annex referred to in the certificate.

4.5.4 The effective date of certification shall not be before the date of decision to grant the certification to the producer group.

4.5.5 The certificate for produce certification shall be for a maximum period of 3 years from the date of decision to grant the produce certification.

4.6 Surveillance

4.6.1 During the surveillance evaluation, the evaluators shall as a minimum check and report on the following;

a) Status of compliance to the requirements of the certification criteria,
b) Internal evaluation reports /audit,

c) Handling and disposal of nonconforming products,
d) Drawing samples for testing in independent laboratory
e) Actions taken on nonconformities observed during the previous evaluation,
f) Redressal of complaints if any,
g) Information on production of produce and the names of consignees to whom certified produce have been supplied.

4.6.2 If any nonconformity is observed, the same shall be categorized as either a Critical, Major or Minor. The nonconformity report shall be provided to the client in writing, generally on site, for correction and corrective action. Details of the same shall be reported in the Surveillance evaluation report.
4.6.3 ISCOP may increase or decrease the frequency of surveillance evaluation based on the performance of the organization. During the validity period of a certificate, ISCOP will carry out an unannounced inspection on a number of producers in the producer group equivalent to 10% of the inspection sample size inspected in the previous announced inspection. Only if the producers inspected externally have no non-conformities raised in that unannounced surveillance inspection, the following regular announced inspection by ISCOP will be reduced to 10% of the original farmer sample size provided the findings from the Quality Management System audit carried out at the following regular announced inspection are also favourable to this reduction. If there are non-conformities raised in the unannounced inspections, in the following regular announced inspection, justification must be given for inspecting only the minimum (square root) sample size, and not an increased sample size.

4.7 Suspension

The provisions of 4.6 will apply except a Partial Suspension may be issued to the group whereby one producer is suspended and not the whole group. A nonconformity is detected at one producer in a producer group, and after ISCOP having investigated by increasing the sample size to determine the seriousness of the nonconformities within the producer group, decided that the one producer is noncompliant.

Step 5: Provisions of Individual Producer/Collector Step 7 to 12 shall apply.

COMPLAINTS & APPEALS

Anyone can send a complaint to ISCOP concerning documentary validation, other client, certified product, scope of services, etc. A response will always be sent to the individual who made the complaint under a reasonable time. All complaints are recorded by the quality manager, as well as measures taken and an analysis is made on a regular basis to improve our service. Upon receipt of the complaint an investigation will be initiated to analyse the root cause in order to implement corrective action plan. Records of complaint are maintained along with the root cause and action taken to resolve the complaint. Once the complaint is resolved, the results are communicated to the complainer by quality manager. The details of the complainer will be kept confidential.

You may appeal any decision on certification by sending a written notice to the quality department, To be eligible, your appeal must:

- Be a written notice (letter or email), - Be done within 15 days, following the receipt of the decision, - Be duly justified: new items that have not yet been brought to the attention must be provided. If the appeal is admissible, it will be processed by the IEI counsel of ISCOP. The decision on appeal is communicated to the interested parties and the decision by IEI counsel remains final and abiding to both the parties. Appeals are not suspensive of the decision subject to the appeal. These decisions therefore apply until a new decision has been made after evaluation of your appeal.

You are responsible for managing third parts claims that are addressed to you directly. You must keep a record of all complaints made known to it relating to compliance with certification requirements and makes these records available to us. These records must keep track of the appropriate action taken and these actions must be documented.

REFERENCE: Scheme Document: VOLUNTARY CERTIFICATION SCHEME FOR MEDICINAL PLANT PRODUCE CERTIFICATION PROCESS - Version II Sep. 2017

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